

K012446

OCT - 3 2001

Charles A. Smith  
811 Starlite Drive  
Louisville, KY 40207

**Non-Confidential Summary of Safety and Effectiveness**

July 2001

Charles A. Smith  
811 Starlite Drive  
Louisville, KY 40207

Tel - 502-969-9652

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<b>Official Contact:</b>	Charles A. Smith
<b>Proprietary or Trade Name:</b>	OBA-1™ MRI - Office Based Anesthesia Unit MRI
<b>Common/Usual Name:</b>	Anesthesia gas machine
<b>Classification Name:</b>	Gas machine, anesthesia
<b>Predicate Devices:</b>	Smith - OBA-1™ - K000859 Dräger - Narkomed MRI Anesthesia System K972848

**Device Description:**

The OBA-1™ MRI is an anesthesia unit which includes these features:

- Can be connected to a central pipeline or cylinder oxygen/air source
- Oxygen flowmeter 0 - 10 L/min
- Air flowmeter 0 - 10 L/min
- Oxygen and air pipeline pressure gauges 0 - 100 psi
- Oxygen Supply Failure Alarm
- Vaporizer - temperature and pressure compensated
- Oxygen Flush valve
- Back Pressure Check valve
- Indexed Fresh Gas Common outlet with safety lock
- Patient Manifold with directional valves - inspiratory and expiratory
- Adjustable APL valve with 19 mm waste gas outlet connection which can be connected to an active scavenging system
- MRI compatible Airway Pressure Gauge
- Oxygen sensor port
- Circuit Pressure monitor and gauge connection ports

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- THERMH<sub>2</sub>OSORB – Sodalime CO<sub>2</sub> absorber
- Bag/Ventilator Switch Valve - 22 mm breathing bag port and 22 mm ventilator hose port

1. Intended use -                      The OBA-1™ MRI is intended to provide continuous gas inhalation for patient requiring anesthesia under the direct care and supervision of a trained and qualified practitioner. It provides for oxygen delivery with an anesthetic agent, via the specific vaporizer, of the practitioner's choice. The OBA-1™ MRI is intended for use in an MRI environment of 1.5 tesla or less. It is to be used with an oxygen monitor and other suitable monitors.
2. Environment of Use -              Physician office; day surgery center; dental office; MRI environment
3. Patient Population -                Patients requiring general anesthesia by inhalation

### Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and legally marketed predicate devices. The most significant attributes have been listed.

A glossary of the predicate devices:

Company	Model	510(k) status
1. Smith	OBA-1™	K000859
2. Penlon	Sigma Elite Vaporizer	K942545
3. Clippard	Oxygen Flush valve	exempt
	One way check valve	exempt
4. Anesthesia Associates	MRI Airway pressure gauge	preamendment
	Bag/Ventilator Switch Valve with APL Valve	preamendment

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	Oxygen sensor port	preamendment
5. Smith	THERMH <sub>2</sub> OSORB	exempt - K954280
6. Porter Instruments	Flowmeters	exempt

<b>Attribute</b>	<b>Proposed device OBA-1 MRI</b>	<b>Predicate Devices are listed under each attribute</b>
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<b>Use</b>
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Intended to provide anesthesia delivery in office or outpatient setting and MRI scanning rooms	Yes	1
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<b>Design</b>
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Can be connected to central pipeline systems or cylinder yokes with regulators	Yes	1
Two gas flowmeters; 1 (oxygen) 1 (air)	Yes	1
Utilizes standard flowmeters	Yes	1, 6
Utilizes a disposable CO <sub>2</sub> absorber canister	Yes	1, 5
Has directional valves (inspiratory/ expiratory)	Yes	1
Incorporates standard 510(k) cleared vaporizers	Yes	1, 2
Has an APL valve with gas scavenging	Yes	1, 4
Manual ventilation via a breathing bag or automatic ventilation with ventilator	Yes	1
Has oxygen monitoring port	Yes	1
Has patient pressure monitoring port	Yes	1

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Attribute	Proposed device OBA-1 MRI	Predicate Devices are listed under each attribute
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### Design (continued)

Connects to standard anesthesia breathing circuits	Yes	1, 5
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Has oxygen flush valve	Yes	1, 3
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### Materials

Materials are standard for use in anesthesia gas machines	Yes	1, 2, 3, 4, 5, 6
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### Packaging

Provided clean, non-sterile	Yes	1, 5
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Can be cleaned and disinfected	Yes	1, 4
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### Performance Standards / Specifications

None applicable under Section 514	Yes	1, 2, 3, 4, 5, 6
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### Differences Between Other Legally Marketed Predicate Devices

There are no functional differences between the proposed device and the legally marketed predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 3 2001

Mr. Charles A. Smith  
811 Starlite Drive  
Louisville, KY 40207

Re: K012446  
OBA-A™ MRI Anesthesia Machine  
Regulation Number: 868.5160  
Regulation Name: Gas Machine For Anesthesia  
Regulatory Class: II (two)  
Product Code: 73 BSZ  
Dated: September 11, 2001  
Received: September 14, 2001

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

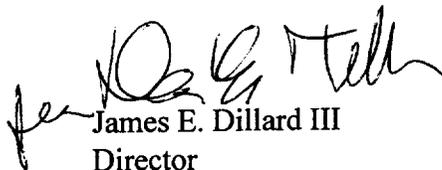
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CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

**510(k) Number:** K012446 (To be assigned)

**Device Name:** Office Based Anesthesia Machine - **OBA-1™ MRI**

**Intended Use :** The Office Based Anesthesia Unit - OBA-1™ MRI is intended for administration of general inhalation anesthesia using mixtures of oxygen, air and volatile anesthetics, and for providing breathing gas and for either spontaneous ventilation or controlled ventilation of patient lungs.

The OBA-1™ MRI can be used in MRI scanner rooms with shielded or unshielded magnets up to 1.5 tesla.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K012446

Prescription Use   
(Per CFR 801.109)

or

Over-the-counter use